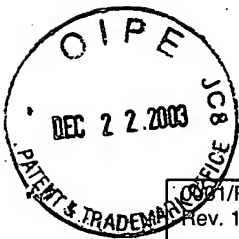


This Information Disclosure Statement is being filed:

- ☒ within three months of the filing date of the application;
- ☐ before the mailing of a first official action after the filing of a request for continued examination (RCE) under 37 CFR § 1.114;
- ☐ after three months of the filing date of this national application or the date of entry of the national stage in an international application, or after the mailing date of the first official action on the merits, whichever event last occurred, but before the mailing date of the first to occur of either: (1) a final action under 37 CFR § 1.113; or (2) an action that otherwise closes prosecution in the application, and:
  - ☐ attached hereto is the fee set forth under 37 CFR § 1.17(p) for submission of this Information Disclosure Statement under 37 CFR § 1.97(c); OR
  - ☐ Applicant certifies pursuant to 37 CFR § 1.97(e) that:
    - ☐ each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement; OR
    - ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 CFR § 1.56(c) more than three months prior to the filing of this Statement;
- ☐ before the payment of the issue fee but after the mailing date of the first to occur of either: (1) a final action under 37 CFR § 1.113; or (2) an action that otherwise closes prosecution in the application, and:
  - ☐ Applicant certifies pursuant to 37 CFR § 1.97(e) that:
    - ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement; or
    - ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application



12-22-03



PTO/SB/21 (modified)  
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<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence during pendency of filed application)</i>		Application Number	10/667,236
		Filing Date	September 17, 2003
		First Named Inventor	Brenda F. Baker <i>et al.</i>
		Group Art Unit Number	Not Yet Known
		Examiner Name	Not Yet Known
Total Number of Pages in This Submission	5**	Attorney Docket Number	23546-08149 (BIOL0019US)

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REMARKS: \*\*IDS references not included in total pages submitted.

SIGNATURE OF ATTORNEY OR AGENT			
Signature:			
Attorney/Reg. No.:	Susan T. Hubl, Ph.D., Reg. No. 47,668	Dated:	December 17, 2003

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PATENT

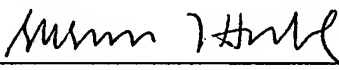
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Brenda F. Baker *et al.*  
APPLICATION NO.: 10/667,236  
FILING DATE: September 17, 2003  
TITLE: MOUSE MODEL FOR ~~TEEM~~ BONE METABOLISM  
EXAMINER: Not yet known  
GROUP ART UNIT: Not yet known  
ATTY. DKT. NO.: 23546-08149 (BIOL0019US)

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**INFORMATION DISCLOSURE STATEMENT**  
**Under 37 CFR §§ 1.56 and 1.97-98**

SIR:

Pursuant to the provisions of 37 CFR §§ 1.56 and 1.97-98, enclosed herewith is modified form PTO/SB/08A listing references for consideration by the Examiner. Enclosed is a copy of each listed reference that may be material to the examination of this application, and for which there may be a duty to disclose.

The filing of this Information Disclosure Statement shall not be construed as a representation regarding the completeness of the list of references, or that inclusion of a reference in this list is an admission that it is prior art or is pertinent to this application, or that a search has been made, or as an admission that the information listed is, or may be considered to be, material to patentability, or that no other material information exists, and shall not be construed as an admission against interest in any manner.

and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated under 37 CFR § 1.56(c) more than three months prior to the filing of this Statement; AND

- ☐ attached hereto is the fee set forth under 37 CFR §1.17(p) for submission of this Information Disclosure Statement under 37 CFR. § 1.97(c); OR
- ☐ after the payment of the issue fee. Applicant request that the information contained in this Information Disclosure Statement be placed in the file according to 37 CFR § 1.97(i), although the information may not be considered by the USPTO.
- ☐ This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application No. [APPLICATION NUMBER], filed on [FILING DATE], and the references cited therein are hereby referenced, but are not required to be provided in this application under 37 CFR § 1.98(d).
- ☐ Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 CFR § 1.56(c) more than thirty days prior to the filing of this Information Disclosure Statement. 37 CFR § 1.704(d).
- ☒ Applicant submits that no fee is required for the consideration of this Information Disclosure Statement.

Consideration of the listed references and favorable action are solicited.

Respectfully submitted,

BRENDA F. BAKER *et al.*

Dated: December 17, 2003

By: 

Susan T. Hubl, Ph.D, Patent Agent

Reg. No. 47,668

Attorney for Applicants

Fenwick & West LLP

Silicon Valley Center

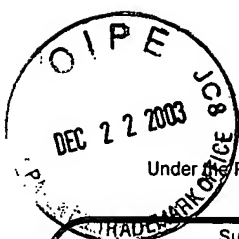
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Submitted 12/17/03

Sheet

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of

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**Complete if Known**

Application N .	10/667,236
Filing Date	September 17, 2003
First Named Inventor	Brenda F. Baker et al.
Art Unit	Not Yet Known
Examiner Name	Not Yet Known
Attorney Docket Number	23546-08149 (BIOL0019US)

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document No. Number - Kind Code <sup>2</sup> (if known)	Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
	A1	US-5,977,101	11/02/1999	Ali et al.
	A2	US-6,017,729	01/25/2000	Anderson et al.

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> - Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T <sup>6</sup>
	B1	WO 01/23559	04/05/2001	Eli Lilly and Company	
	B2	WO 02/16551	02/28/2002	University of Massachusetts Medical Center	

**OTHER REFERENCES - NON-PATENT LITERATURE DOCUMENTS**

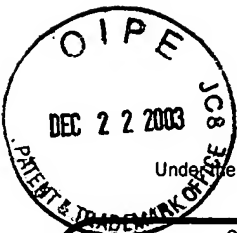
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	C1	Anderson, D. M. et al., 'A homologue of the TNF receptor and its ligand enhance T-cell growth and dendritic-cell function,' <i>Nature</i> , Vol. 390, November 13, 1997, 175-179.	
	C2	Burgess, T. L. et al., 'The Ligand for Osteoprotegerin (OPGL) Directly Activates Mature Osteoclasts,' <i>The Journal of Cell Biology</i> , Vol. 145, No. 3, May 3, 1999, 527-538.	
	C3	Fata, J. E., et al., 'The Osteoclast Differentiation Factor Osteoprotegerin-Ligand Is Essential for Mammary Gland Development,' <i>Cell</i> , Vol. 103, September 29, 2000, 41-50.	
	C4	Fuller, K. et al., 'TRANCE Is Necessary and Sufficient for Osteoblast-mediated Activation of Bone Resorption in Osteoclasts,' <i>J. Exp. Med.</i> , Vol. 188, No. 5, September 7, 1998, 997-1001.	
	C5	Gori, F. et al., 'The Expression of Osteoprotegerin and RANK Ligand and the Support of Osteoclast Formation by Stromal-Osteoblast Lineage Cells Is	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

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Application N	10/667,236
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Examiner Name	Not Yet Known
Attorney Docket Number	23546-08149 (BIOL0019US)

Sheet 2 of 4

**OTHER REFERENCES – NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		Developmentally Regulated*, <i>Endocrinology</i> , Vol. 141, No. 12, 2000, 4768-4776.	
	C6	Hofbauer, L.C. et al.; "Stimulation of Osteoprotegerin Ligand and Inhibition of Osteoprotegerin Production by Glucocorticoids in Human Osteoblastic Lineage Cells: Potential Paracrine Mechanisms of Glucocorticoid-Induced Osteoporosis*, <i>Endocrinology</i> , Vol. 140, No. 10, 1999, 4382-4389.	
	C7	Hsu, H. et al., 'Tumor necrosis factor receptor family member RANK mediates osteoclast differentiation and activation induced by osteoprotegerin ligand,' <i>Proc. Natl. Acad. Sci. USA</i> , Vol. 96, March 1999, 3540-3545.	
	C8	Itonaga, I. et al., "Rheumatoid arthritis synovial macrophage-osteoclast differentiation is osteoprotegerin ligand-dependent,' <i>Journal of Pathology</i> , 2000: 192, 97-104.	
	C9	Kartsogiannis, V. et al., "Localization of RANKL (Receptor Activator of NFkB Ligand) mRNA and Protein in Skeletal and Extraskelatal Tissues,' <i>Bone</i> , Vol. 25, No. 5, November 1999, 525-534.	
	C10	Khosla, S., 'Minireview: The OPG/RANKL/RANK System,' <i>Endocrinology</i> 142 (12), December 2001, 5050-5055.	
	C11	Komarova, S.V., et al., 'RANK Ligand-induced Elevation of Cytosolic Ca <sup>2+</sup> Accelerates Nuclear Translocation of Nuclear Factor kB in Osteoclasts*, <i>The Journal of Biological Chemistry</i> , Vol. 278, No. 10, March 7, 2003, 8286-8293.	
	C12	Kong, Y. Y. et al., 'Osteoprotegerin ligand: a regulator of immune responses and bone physiology,' <i>Viewpoint Immunology Today</i> , Vol. 21, No. 10, October 2000, 495-502.	
	C13	Kong, Y. Y. et al., 'Activated T cells regulate bone loss and joint destruction in adjuvant arthritis through osteoprotegerin ligand,' <i>Nature</i> , Vol. 402, November 18, 1999, 304-309.	
	C14	Kong, Y. Y. et al., 'OPGL is a key regulator of osteoclastogenesis, lymphocyte development and lymph-node organogenesis,' <i>Nature</i> , Vol. 397, January 28, 1999, 315-323.	

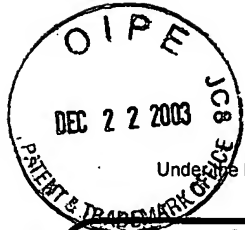
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23546/08149/DOCS/1379225.1



<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>Submitted 12/17/03</i>		<b>Complete if Known</b>			
		Application No.	10/667,236		
		Filing Date	September 17, 2003		
		First Named Inventor	Brenda F. Baker et al.		
		Art Unit	Not Yet Known		
		Examiner Name	Not Yet Known		
Sheet	3	of	4	Attorney Docket Number	23546-08149 (BIOL0019US)

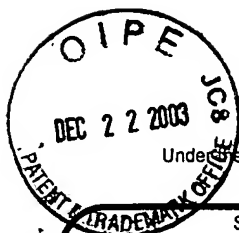
OTHER REFERENCES – NON-PATENT LITERATURE DOCUMENTS			
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	C15	Lacey, D. L. et al., "Osteoprotegerin Ligand Is a Cytokine that Regulates Osteoclast Differentiation and Activation," <i>Cell</i> , Vol. 93, April 17, 1998, 165-176.	
	C16	Lee, S. K. and Lorenzo, J.A., 'Parathyroid Hormone Stimulates TRANCE and Inhibits Osteoprotegerin Messenger Ribonucleic Acid Expression in Murine Bone Marrow Cultures: Correlation with Osteoclast-Like Cell Formation*,' <i>Endocrinology</i> , Vol. 140, No. 8, © 1999, 3552-3561.	
	C17	Lum, Lawrence et al., 'Evidence for a Role of a Tumor Necrosis Factor- $\alpha$ (TNF- $\alpha$ )-CONVERTING enzyme-like Protease in Shedding of TRANCE, a TNF Family Member Involved in Osteoclastogenesis and Dendritic Cell Survival*,' <i>The Journal of Biological Chemistry</i> , Vol. 274, No. 19, May 7, 1999, 13613-13618.	
	C18	Ma, Y.L. et al., 'Catabolic Effects of Continuous Human PTH (1-38) in Vivo is Associated with Sustained Stimulation of RANKL and Inhibition of Osteoprotegerin and Gene-associated Bone Formation,' <i>Endocrinology</i> 14299, ©2001, 4047-4054.	
	C19	Menea, C. et al., 'Enhanced RANK ligand expression and responsivity of bone marrow cells in Paget's disease of bone,' <i>The Journal of Clinical Investigation</i> , Vol. 105, No. 12, June 2000, 1833-1838.	
	C20	Nagai, M. et al., 'Cancer Cells Responsible for Humoral Hypercalcemia Express mRNA Encoding a Secreted Form of ODF/TRANCE That Induces Osteoclast Formation,' <i>Biochemical and Biophysical Research Communications</i> 269, No. 2, © 2000, 532-536.	
	C21	Nakashima, T., 'RANKL and RANK as novel therapeutic targets for arthritis,' ISSN 1040-8711 ©2003 Lippincott Williams & Wilkins, 280-287.	
	C22	Pearse, R. N. et al., 'Multiple myeloma disrupts the TRANCE/osteoprotegerin cytokine axis to trigger bone destruction and promote tumor progression,' <i>PNAS</i> , Vol. 98, No. 20, September 25, 2001, 11581-11586.	
	C23	Rosen, C. J. and BILEZIKIAN, J. P., 'Anabolic Therapy for Osteoporosis,' <i>The</i>	

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT***Submitted 12/17/03***Complete if Known**

Applicati n No.	10/667,236
Filing Date	September 17, 2003
First Named Inventor	Brenda F. Baker et al.
Art Unit	Not Yet Known
Examiner Name	Not Yet Known
Attorney Docket Number	23546-08149 (BIOL0019US)

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**OTHER REFERENCES – NON-PATENT LITERATURE DOCUMENTS**

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		<i>Journal of Clinical Endocrinology &amp; Metabolism</i> , Vol. 86, No. 3, © 2001, 957-964.	
	C24	Russell, R. G. G. et al., 'The Influence of Pyrophosphate, Condensed Phosphates, Phosphonates and other Phosphate Compounds on the Dissolution of Hydroxyapatite <i>in vitro</i> and on Bone Resorption Induced by Parathyroid Hormone in Tissue Culture and in thyroparathyroidectomised Rats,' <i>Calc. Tiss. Res.</i> , 6, © 1970, 183-196.	
	C25	Swarthout, J. T. et al., 'Parathyroid hormone-dependent signaling pathways regulating genes in bone cells,' <i>Gene</i> 282 (2002), 1-17.	
	C26	Walsh, M.C. and Choi, Yongwon, 'Biology of the TRANCE axis,' <i>Cytokine &amp; Growth Factor Reviews</i> 14, © 2003, 251-263.	
	C27	Wang, R. et al., 'Regulation of activation-induced receptor activator of NF-κB ligand (RANKL) expression in T cells,' <i>Eur. J. Immunol.</i> , 2002, 32, 1090-1098.	
	C28	Wong, B. R. et al., 'TRANCE' (tumor Necrosis Factor [TNF]-related Activation-induced Cytokine), a New TNF Family Member Predominantly Expressed in T cells, Is a Dendritic Cell-specific Survival Factor,' <i>J. Exp. Med.</i> , Vol. 186, No. 12, December 15, 1997, 2075-2080.	
	C29	Wong, B. R et al., 'TRANCE Is a Novel Ligand of the Tumor Necrosis Factor Receptor Family That Activates c-Jun N-terminal Kinase in T Cells*,' <i>The Journal of Biological Chemistry</i> , Vol. 272, No. 40, October 3, 1997, 25190-25194.	
	C30	Yasuda, H. et al., 'Osteoclast differentiation factor is a ligand for osteoprotegerin/osteoclastogenesis-inhibitory factor and is identical to TRANCE/RANKL,' <i>Proc. Natl. Aca. Sci. USA</i> , Vol. 95, March 1998, 3597-3602.	

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